

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT  
INFRINGEMENT LITIGATION

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C.A. No. 05-356-KAJ  
(consolidated)

**NOTICE OF DEPOSITION AND SUBPOENA OF  
COBALT PHARMACEUTICALS, INC. PURSUANT TO  
FEDERAL RULE OF CIVIL PROCEDURE 45**

**PLEASE TAKE NOTICE** that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen") will take the deposition upon oral examination of Cobalt Pharmaceuticals, Inc. at the offices of Esquire Deposition Services, 99 Summer Street, Suite 804, Boston, Massachusetts 02110 beginning at 10:00 A.M. on June 13, 2006.

NOTICE IS FURTHER GIVEN THAT the deposition will be recorded stenographically through instant visual display of testimony (real-time), by certified shorthand reporter and notary public or such other person authorized to administer oaths under the laws of the United States, and shall continue from day to day until completed. This deposition will be videotaped.

NOTICE IS FURTHER GIVEN THAT pursuant to the Federal Rules of Civil Procedure, Janssen will serve upon Cobalt Pharmaceuticals, Inc. a Subpoena in a Civil Case. Attached hereto as Exhibit A is a true and correct copy of that Subpoena.

ASHBY & GEDDES

*/s/ Tiffany Geyer Lydon*

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Steven J. Balick (I.D. #2114)  
John G. Day (I.D. #2403)  
Tiffany Geyer Lydon (I.D. #3950)  
Lauren E. Maguire (I.D. #4261)  
222 Delaware Avenue, 17<sup>th</sup> Floor  
P.O. Box 1150  
Wilmington, DE 19899  
(302) 654-1888

*Attorneys for Janssen Pharmaceutica N.V., Janssen,  
L.P., and Synaptech, Inc.*

Dated: May 26, 2006

169938.1

# EXHIBIT A

A088 Subpoena in a Civil Case

Issued by the  
**United States District Court**  
**District of Massachusetts**

IN RE: '318 PATENT INFRINGEMENT  
 LITIGATION

**SUBPOENA IN A CIVIL CASE**

Case Number:<sup>1</sup> C.A. No. 05-356-KAJ (consolidated)  
 (District of Delaware)

TO: Cobalt Pharmaceuticals, Inc.  
 c/o Dr. James Parker  
 Strategic Bioscience Corporation  
 93 Birch Hill Road  
 Stow, MA 01775

- ☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY

COURTROOM

DATE AND TIME

- ☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION Recording Method: By stenographer and videotape

DATE AND TIME

Esquire Deposition Services, 99 Summer Street, Suite 804, Boston, MA 02110

JUNE 13, 2006 AT 10:00 A.M.

- ☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): Please See Schedule B Attached

PLACE

DATE AND TIME

- ☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES

DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)  
 Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc.

DATE AND TIME  
 May 26, 2006

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER  
 Tiffany Geyer Lydon, Ashby & Geddes, 222 Delaware Avenue, 17th Floor  
 Wilmington, DE 19899  
 Tel: 302-654-1888

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

<sup>1</sup> If action is pending in district other than district of issuance, state district under case number.

A088 Subpoena in a Civil Case

**PROOF OF SERVICE**

DATE	PLACE
SERVED	
SERVED ON (PRINT NAME)	MANNER OF SERVICE
SERVED BY (PRINT NAME)	TITLE

**DECLARATION OF SERVER**

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on

DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

**Rule 45, Federal Rules of Civil Procedure, Parts C&D****(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.**

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance,
- (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to

the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

**(d) DUTIES IN RESPONDING TO SUBPOENA.**

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

**SCHEDULE A**

**DEFINITIONS**

1. As used herein, “the ‘318 patent” shall mean United States Patent No. 4,663,318.
2. As used herein, “ANDA” shall mean Abbreviated New Drug Application Number 77-823.
3. As used herein, “Plaintiffs” refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.
4. As used herein, “You,” “Your,” or “Yours,” shall mean Ranbaxy, Inc, Ranbaxy, Inc.’s corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Ranbaxy, Inc. or its successors.

**TOPICS**

1. The notice You sent to Plaintiffs on October 14, 2005, attached hereto as Exhibit 1.
2. Your patent certification regarding the ‘318 patent in connection with ANDA No. 77-823.

# EXHIBIT 1



**COBALT**

Via FedEx International Priority Service, Return Receipt Requested and  
Certified US Mail, Return Receipt Requested.

October 14, 2005

Mr. Ajit Shetty  
President and Chief Executive Officer  
Janssen Pharmaceutica, Inc.  
Janssen, L.P.  
1125 Trenton-Harbourton Road  
Titusville, NJ  
08560  
Via Certified Mail Return Receipt Requested

Audley A. Ciamporero, Jr.  
JOHNSON & JOHNSON  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
Via Certified Mail Return Receipt Requested

Mr. Ajit Shetty  
President and Chief Executive Officer  
Janssen Pharmaceutica, NV  
Turnhoutseweg 30  
B-2340 Beerse  
BELGIUM  
VIA Federal Express

**RE:** Notice Pursuant to 21 U.S.C. 355(j)(2)(B)(i) and (ii) [21 C.F.R. 314.95]  
Galantamine Hydrobromide Tablets, 4 mg, 8 mg and 12 mg Galantamine Base  
Factual and Legal Basis for Cobalt Pharmaceuticals, Inc.'s Assertion of  
Invalidity, Unenforceability or Non-Infringement of  
U.S. Patents 6,099,863 and 6,358,527

Dear Sir:

Please be advised that the Food and Drug Administration has acknowledged receipt of an Abbreviated New Drug Application (ANDA) number 77-823, submitted on behalf of Cobalt Pharmaceuticals, Inc. (Cobalt) pursuant to 21 U.S.C. 355(j) (the Cobalt ANDA). Cobalt is seeking approval of 4 mg, 8 mg and 12 mg galantamine base dosage forms of Galantamine Hydrobromide Tablets for treatment

6500 KITIMAT ROAD  
MISSISSAUGA, ONTARIO  
CANADA, L5N 2B8

905 814 1820 1 866 254 6111 905 814 8696



Janssen Pharmaceutica, Inc.  
Johnson & Johnson  
Janssen Pharmaceutica, NV  
October 14, 2005  
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of Alzheimer's Disease. Any required bio-availability or bio-equivalence data or information has been submitted in connection with the above noted Cobalt ANDA.

This will advise that Cobalt filed a patent certification pursuant to 21 U.S.C. 355(j)(2)(A)(vii)(IV) and 21 C.F.R. 314.94(a)(12)(i)(A)(4) in support of the Cobalt ANDA. We understand that Janssen Pharmaceutica NV (Janssen) is the holder of the approved NDA No. 21-169 for Galantamine Hydrobromide Tablets and is the record assignee of U.S. Patent No. 6,099,863 (the '863 patent). We also understand that Janssen is the owner of U.S. Patent 6,358,527 (the '527 patent), by virtue of the fact that the '527 patent issued from a continuation application of the '863 patent. We believe that Janssen Pharmaceutica, Inc., or Janssen, L.P. may be the U.S. representative for Janssen Pharmaceutica NV. The assignment record for the '863 patent, also lists Audley A. Ciamporero, Jr., at Johnson & Johnson, as the correspondent for Janssen in connection with the '863 patent. Accordingly, this notice is being provided to each of the noted entities.

In accordance with the statutory and regulatory requirements, Cobalt provides the following information:

1. The Food and Drug Administration (FDA) has received an ANDA submitted on behalf of Cobalt containing the required bioavailability or bioequivalence data or information with respect to Galantamine Hydrobromide Tablets.
2. The Cobalt ANDA number is 77-823.
3. The established name of the proposed drug product, as defined in 21 U.S.C. 352(e)(3), is Galantamine Hydrobromide Tablets.
4. The active ingredient, strength and dosage form of the proposed drug product is Galantamine Hydrobromide, containing 4 mg, 8 mg and 12 mg Galantamine base in tablet form for oral administration.

Janssen Pharmaceutica, Inc.  
Johnson & Johnson  
Janssen Pharmaceutica, NV  
October 14, 2005  
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5. The patent numbers<sup>1</sup> and expirations dates, as known and understood by Cobalt, of the patents alleged to be invalid, unenforceable or not infringed are:

U.S. Patent 6,099,863 (the '863 patent), which expires on June 6, 2017, and

U.S. 6,358,527 (the '527 patent), which expires on June 6, 2017.

6. The information detailed in the appended memorandum is supplied for the sole purpose of complying with the above-referenced statutes and regulations, and neither Cobalt, nor its attorneys, waive any attorney-client privilege or any attorney work product immunity concerning the subject matter of this communication.
7. Cobalt has identified Dr. James Parker, Strategic Bioscience Corporation; 93 Birch Hill Road; Stow, MA 01775 as its U.S. Agent for ANDA 77-823
8. Cobalt reserves the right to supplement this letter and the appended memorandum further detailing the factual and legal bases of invalidity, non-enforceability and non-infringement of the 863 and '527 patents should subsequent investigations reveal additional grounds thereof. Thus, nothing in this letter or the appended memorandum should be considered a waiver of any additional basis for supporting the conclusion that Cobalt's Galantamine Hydrobromide Tablets do not infringe either the '863 or the '527 patent or a waiver of any additional basis supporting a conclusion that the patents are invalid or unenforceable.

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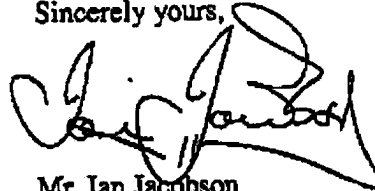
<sup>1</sup> Please be advised that Cobalt is not seeking FDA approval for Cobalt's Galantamine Hydrobromide Tablets until U.S. Patent 4,663,318 (the '318 patent) expires. Cobalt understands that the '318 patent will expire on December 14, 2008 (information obtained from the *Orange Book* listing for NDA No. 21-169).

Janssen Pharmaceutica, Inc.  
Johnson & Johnson  
Janssen Pharmaceutica, NV  
October 14, 2005  
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An applicant for an ANDA is required to make certification with respect to patents owned or licensed by the NDA holder and which are published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the *Orange Book*), relating to Janssen's Razadyne® Tablet product.<sup>2</sup> Cobalt has certified that the '863 patent and the '527 patent, which are listed in the *Orange Book*, or the corresponding Electronic Orange Book for the various Razadyne® Tablet products are invalid, unenforceable or not infringed.

Attached hereto is a memorandum detailing Cobalt's factual and legal basis supporting its Paragraph IV Certification.

Sincerely yours,



Mr. Ian Jacobson  
Chief Operating Officer  
Cobalt Pharmaceuticals, Inc.

JMS/

Enclosure

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<sup>2</sup> Until this year, Janssen marketed its galantamine hydrobromide tablets under the trademark REMINYL®.

**CERTIFICATE OF SERVICE**

I hereby certify that on the 26th day of May, 2006, the attached **NOTICE OF DEPOSITION AND SUBPOENA OF COBALT PHARMACEUTICALS, INC.** **PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45** was served upon the below-named counsel of record at the address and in the manner indicated:

John W. Shaw, Esquire  
Young Conaway Stargatt & Taylor, LLP  
The Brandywine Building  
1000 West Street, 17<sup>th</sup> Floor  
Wilmington, DE 19801

HAND DELIVERY

Daniel F. Attridge, P.C.  
Kirkland & Ellis LLP  
655 15<sup>th</sup> Street, N.W.  
Washington, DC 20005-5793

VIA FEDERAL EXPRESS

Mary B. Matterer, Esquire  
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HAND DELIVERY

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HAND DELIVERY

Alan H. Bernstein, Esquire  
Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.  
1635 Market Street, 12<sup>th</sup> Floor  
Philadelphia, PA 19103

VIA FEDERAL EXPRESS

*/s/ Tiffany Geyer Lydon*

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Tiffany Geyer Lydon